NONCONFIDENTIAL
04-1323, -1487

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ARTHROCARE CORPORATION,

Plaintiff/Counterclaim Defendant-Appellee,

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

v.

SMITH & NEPHEW, INC.,

Defendant/Counterclaimant-Appellant.

Appeal from the United States District Court for the District of Delaware in Case No. 01-CV-504, Chief Judge Sue L. Robinson

---

BRIEF FOR PLAINTIFF/COUNTERCLAIM DEFENDANT-APPELLEE ARTHROCARE CORPORATION

Matthew D. Powers
Jared Bobrow
Perry Clark
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000

Timothy E. DeMasi
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153
(212) 310-8000

Jack B. Blumenfeld
Karen Jacobs Louden
MORRIS, NICHOLS, ARSHT & TUNNELL
1201 North Market Street
Wilmington, DE 19899
(302) 658-9200

Attorneys for ArthroCare Corporation

CERTIFICATE OF INTEREST

Counsel for Plaintiff/Counterclaim Defendant-Appellee

ArthroCare Corporation certifies the following information in compliance with Rule 26.1 of the Federal Rules of Appellate Procedure and Rules 26.1 and 47.4 of the Federal Circuit Rules, and in satisfaction of Rule 12(b) of the Federal Rules of Appellate Procedure requiring a Representation Statement:

1. The full name of every party represented by me is: ArthroCare Corporation.

2. The names of the real parties in interest represented by me are the same as those identified in paragraph 1 above.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party represented by me are: None.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this Court are:

Weil, Gotshal & Manges LLP attorneys:
Matthew D. Powers
Jared Bobrow
Timothy E. DeMasi
Perry Clark
David Pollock

Morris, Nichols, Arsht & Tunnell attorneys:
Jack B. Blumenfeld
Karen Jacobs Louden
James W. Parrett, Jr.

Dated: November 15, 2004

Respectfully submitted,

By: _____

Jared Bobrow
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000

Attorneys for Plaintiff/Counterclaim Defendant-Appellee ArthroCare Corporation

TABLE OF CONTENTS

CONFIDENTIAL INFORMATION OMITTED

The material omitted from pages 10-11 and 65-68 describes the terms of ArthroCare's and Ethicon's confidential settlement agreement.

TABLE OF AUTHORITIES

CASES

STATUTES

STATEMENT OF RELATED CASES

Under Federal Circuit Rule 47.5, counsel for plaintiff/counterclaim defendant-appellee ArthroCare Corporation ("ArthroCare") states that no other appeal in or from the same district court proceedings was previously before this or any other appellate court, except for ArthroCare's conditional cross-appeal on the doctrine of equivalents (No. 04-1352), which was dismissed by order dated June 15, 2004. No other case is known to counsel for ArthroCare to be pending in this or any other court that will directly affect or be directly affected by this Court's decision in the pending appeal.

STATEMENT OF JURISDICTION

The district court had jurisdiction in this case under 28 U.S.C. §§ 1331 and 1338(a). This Court has jurisdiction over this appeal under 28 U.S.C. §§ 1292(c) and 1295(a)(1).

STATEMENT OF THE ISSUES

1. Did Smith & Nephew waive its right to challenge the jury's verdict on the validity of the '536 and '882 patents when it failed to move for judgment as a matter of law on validity before the case was submitted to the jury?

2. Whether a reasonable jury could have found that Smith & Nephew failed to carry its burden of proving by clear and convincing evidence that the Roos Article and the Roos Patent disclose each and every limitation of the asserted claims of the '536 patent?

3. Whether a reasonable jury could have found, under the unchallenged claim constructions and jury instructions, that the use of the accused products infringes the asserted claims of the '592 patent?

4. Whether a reasonable jury could have found that Smith & Nephew failed to carry its burden of proving by clear and convincing evidence that the Certificate of Correction for the '882 patent was invalid?

5. Whether the district court properly determined that the antitrust counterclaim as pleaded by Smith & Nephew failed to state a claim as a matter of law?

STATEMENT OF THE CASE

ArthroCare filed this patent infringement suit against Smith & Nephew on July 21, 2001 alleging infringement of U.S. Patent Nos. 5,697,536 ("'536 patent"), 5,697,882 ("'882 patent"), and 6,224,592 ("'592 patent"). On July 30, 2002, Smith & Nephew moved to amend its answer to add an antitrust counterclaim. A1325-54. On November 22, 2002, the district court granted this motion, and bifurcated trial of the antitrust counterclaim, damages, and willfulness until after the trial on infringement and validity. A3334-36.

This case was tried to a jury over nine days from April 30 to May 12, 2003. On the sixth day of trial, Smith & Nephew moved for judgment as a matter of law ("JMOL") on infringement under Fed. R. Civ. P. 50(a). A15441 (1161:22-25). Before the verdict, Smith & Nephew never moved for JMOL on validity.

The jury returned a verdict in favor of ArthroCare, answering each of the 107 special verdict questions in ArthroCare's favor, finding that Smith & Nephew infringed all of the asserted claims, and finding that all of the asserted claims were not invalid. A369-78.

After the jury's verdict, ArthroCare moved to dismiss Smith & Nephew's antitrust counterclaim. The district court granted the motion on March 10, 2004. A32. On March 12, 2004, Smith & Nephew moved for

reconsideration of the dismissal. A18275-83. On April 27, 2004, the district court denied Smith & Nephew's motion for reconsideration. A146.

Also on March 10, 2004, the district court granted ArthroCare's motion for permanent injunction. A1215-25. On June 24, 2004, the district court issued a permanent injunction, with a specified transition period. A155-163. On April 29, 2004, Smith & Nephew made an emergency motion to this Court to stay enforcement of the injunction. A14094-97. A three judge motion panel denied this motion on June 3, 2004.

STATEMENT OF FACTS

ArthroCare was a company that was created to market and sell its founders' innovative systems and methods for treating tissue through electrosurgery. This suit came about after ArthroCare successfully developed a market for its electrosurgical devices beginning in 1995. Smith & Nephew entered the market in 2001 with full knowledge of ArthroCare's patents and products.

I. ARTHROCARE'S PIONEERING PATENTS

The patents-in-suit cover novel electrosurgical systems and methods for treating tissue using radio frequency ("RF") electrical energy. The field of electrosurgery can be divided between "monopolar" and "bipolar" procedures. A391 (1:28-33).

In monopolar procedures, a treatment ("active") electrode is placed near the target tissue. A15084-85 (230:20-231:16). Current flows from the active electrode to the target tissue to be treated and through the patient's body to a return electrode on the patient's skin. *Id.* Conventionally, monopolar procedures were performed in electrically nonconducting fluids, such as air or glycine. *Id.*

In prior art bipolar procedures, both electrodes conventionally were put in contact with the target tissue. A391 (1:60-66). A common prior art bipolar device was a bipolar forceps, which squeezed tissue between two electrodes and passed current through the tissue. A15085 (232:9-18).

Prior art monopolar and bipolar electrosurgical devices both had certain drawbacks when used in arthroscopic procedures. In these procedures, the joint to be treated is filled with fluid. Doctors prefer to use isotonic saline, an electrically conducting fluid, because it is physiologically compatible with joint tissue. A391 (2:9-14). Using saline, however, can "short" prior art monopolar and bipolar devices and cause unwanted tissue effects. A391 (2:15-20).

ArthroCare's patents-in-suit claim systems and methods that allow electrosurgery to be performed in electrically conducting fluids. In the '536 patent, for example, this is achieved generally by delivering electrically

conducting fluid from a fluid supply to the target site, positioning an active electrode near the target tissue in the presence of the electrically conducting fluid, positioning a return electrode in the fluid away from the tissue, and applying a high frequency voltage to create a current flow path between the active and return electrodes. A399 (18:14-37.

II. ARTHROCARE'S MARKET AND TECHNOLOGY LEADERSHIP

ArthroCare was founded in 1993 by the named inventors of the patents-in-suit, Philip Eggers and Dr. Hira Thapliyal. A15093 (263:23-264:1). When ArthroCare began selling bipolar products embodying the claimed inventions in 1995, it was "[f]irst to market with bipolar ablation." A23626; A15094 (267:14-268:6). As Smith & Nephew acknowledged, ArthroCare's products were the "'gold standard' for product performance." A23090.

In 1998, Smith & Nephew was the world's largest arthroscopy company, but it lacked a bipolar RF product. A15225-26 (616:25-618:10). Smith & Nephew approached ArthroCare to discuss how ArthroCare's technology could "fill the hole" in Smith & Nephew's product line. A15227 (622:10-23). On August 10, 1998, the companies met at ArthroCare's headquarters and Smith & Nephew was highly complimentary of ArthroCare's products and its patents. A15227 (622:24-624:7). Smith & Nephew later informed its sales force of ArthroCare's "strong patent position." A23626.

After their meeting, Smith & Nephew requested some of ArthroCare's newest arthroscopy probes "for testing," and ArthroCare provided them to Smith & Nephew along with documents marked with the patent numbers of the '536 and '882 patents. A15228-29 (628:8-632:19).

III. THE ACCUSED PRODUCTS

Smith & Nephew began selling its Control RF product in July 2001. A15206 (540:3-9). Thereafter, Smith & Nephew launched its ElectroBlade and Saphyre products in March and April of 2002, respectively. *Id.* The Control RF and Saphyre are bipolar RF ablation probes. A23144; A22675. The ElectroBlade is a bipolar RF resection and coagulation probe. A22613.

All of the accused products have a tissue treatment electrode, called an active electrode, located near the distal end of the shaft. A15149 (396:14-398:24); A15151 (404:4-406:6); A15153 (411:7-412:14). Each accused product also has a return electrode, which is spaced back from the active electrode. *Id.* This axial spacing reduces contact between the return electrode and the patient's tissue. *Id.* All of the accused products are designed for use in arthroscopic surgical procedures and thus are intended to be used in joint spaces that are filled with electrically conducting fluid, such as saline or Ringer's lactate. *Id.* In operation, when an RF voltage is applied, the

electrically conducting fluid creates a current flow path between the active and return electrodes. *Id.*

IV. THE '536 PATENT REEXAMINATION

In 1999, a third party initiated reexamination proceedings against the '536 patent. A21671-73. The reexamination was based on U.S. Patent No. 4,116,198 to Roos ("Roos Patent") -- the same patent on which Smith & Nephew based its anticipation defense at trial.

On November 15, 2002, after review by a board of primary examiners, the Patent Office issued a detailed office action which concluded specifically that the Roos Patent did not anticipate or render obvious the '536 patent claims because it does not disclose the use of electrically conducting fluid. A21877-86.

The Patent Office issued a Notice of Intent to Issue Ex Parte Reexamination Certificate confirming all of the '536 claims on March 14, 2003. A22232-35. Thereafter, the Patent Office issued a reexamination certificate.

V. THE '882 PATENT CERTIFICATE OF CORRECTION

On November 22, 1995, ArthroCare filed the application that matured into the '882 patent. Claim 23 of the application, which would issue as claim 1, claimed a method that uses only two electrodes, an "active

electrode" and a "return electrode." A21318-19. Before any examination on the merits, ArthroCare twice amended claim 23. In the second amendment, ArthroCare made two obvious clerical errors. A21471-72. ArthroCare realized its mistakes when the '882 patent issued, and immediately filed a request for a certificate of correction. A21506-07. The Patent Office reviewed the request and granted it, finding that the changes requested would not "constitute new matter or require reexamination of the application" or "materially affect the scope or meaning of the claims allowed by the examiner in the patent." A21509.

VI. ETHICON LITIGATION AND SETTLEMENT

In 1998, ArthroCare sued Ethicon, Inc. in the Northern District of California alleging infringement of four of its patents, including the '536 and '882 patents. A13262. ArthroCare moved for a preliminary injunction and, on December 2, 1998, the district court denied ArthroCare's motion in a non-binding interlocutory order. A13261. The parties continued to litigate and, shortly before trial, entered into a settlement agreement ("Settlement Agreement") on June 28, 1999. A1469-1500.

In addition to concluding the litigation, the Settlement Agreement provided Ethicon with [

CONFIDENTIAL MATERIAL OMITTED FROM THIS PAGE

CONFIDENTIAL MATERIAL OMITTED FROM THIS PAGE

]

On June 28, 2000, ArthroCare granted Stryker Corporation a license to its patents, thus [

.]

SUMMARY OF ARGUMENT

Smith & Nephew brings a very limited challenge on appeal. Smith & Nephew does not challenge the district court's claim constructions on appeal. Smith & Nephew's also does not challenge the district court's jury instructions. Smith & Nephew sole contention is that, although the jury heard from 18 witnesses and received over 110 exhibits over the course of a nine-day trial, the jury's verdict is not supported by substantial evidence. To support its position, Smith & Nephew ignores evidence that directly supports the verdict, fails to view the evidence in the light most favorable to ArthroCare, misapplies

the district court's claim constructions, and ignores its clear and convincing burden of proof.

As a threshold matter, Smith & Nephew cannot challenge the jury's verdict that the '536 and the '882 patents are not invalid. Before the district court submitted the case to the jury, Smith & Nephew failed to move for JMOL on invalidity. By failing to comply with Rule 50(a) of the Federal Rules of Civil Procedure, Smith & Nephew waived its right to challenge the jury verdict on the ground that it purportedly is not supported by substantial evidence.

On the merits, Smith & Nephew's only challenge concerning the '536 patent is to the jury's verdict that the claims are not anticipated. Smith & Nephew asserts that two prior art references – the Roos Patent and the Roos Article – disclose each claim limitation. But Smith & Nephew reaches this conclusion by construing the evidence in its favor, not in ArthroCare's favor as the law requires. The admissions of Smith & Nephew's expert, the Patent Office's confirmation on reexamination that the Roos Patent does not anticipate the '536 claims, and the references themselves make clear that a reasonable jury could find that Smith & Nephew failed to carry its clear and convincing burden of proof.

Smith & Nephew's sole challenge concerning the '592 patent is to

the jury's verdict of infringement. Smith & Nephew argues that the accused devices do not infringe because they perform the claimed methods only for short periods of time. This argument fails on at least two grounds. First, the argument is legally unfounded, because the district court's unchallenged claim construction expressly provides that "[t]he claimed method does not contain any time limitations." This means that short periods of infringement are nonetheless infringing. Second, the evidence did not merely show short periods of infringement. Rather, there was substantial evidence (design documents, videotapes, testimony from Smith & Nephew witnesses, and testimony from expert witnesses) that there were substantial periods of time when all three method steps were performed together.

Smith & Nephew's only challenge concerning the '882 patent is to the jury's verdict that the Certificate of Correction of claim 1 was not invalid. Despite its burden of proof by clear and convincing evidence, Smith & Nephew did not offer a shred of evidence to show that the Certificate was somehow improper. Its lawyer arguments on appeal are unavailing, because the claim's text, the specification, and the prosecution history all demonstrate that original claim 1 contained clerical errors and that those clerical errors were properly corrected.

In a last-ditch effort to set aside the injunction, Smith & Nephew

argues that the district court erred in dismissing its antitrust counterclaim for failure to state a claim. But in making this argument, Smith & Nephew relies on an antitrust theory that it never pleaded. In determining whether a claim is stated, a court may only consider what is pleaded; it may not rely on allegations in briefs, motions, or other parts of the record. The entire thrust of Smith & Nephew's pleaded counterclaim was that ArthroCare and Ethicon agreed to institute this lawsuit as an anticompetitive weapon. This claim fails under the *Noerr-Pennington* doctrine, because the jury verdict in ArthroCare's favor establishes as a matter of law that this lawsuit was not a "sham."

Accordingly, the Court should affirm the district court's denial of JMOL and affirm the dismissal of the antitrust counterclaim.

ARGUMENT

I.

STANDARDS OF REVIEW

In reviewing the denial of JMOL, the test is "whether viewing the evidence in the light most favorable to the non-moving party, and giving the non-movant the benefit of all reasonable inferences, there is sufficient evidence of record to support the jury verdict in favor of the non-movant." *Minnesota Min. & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1300 (Fed. Cir. 2002); *accord Buskirk v. Apollo Metals*, 307 F.3d 160, 166 (3d Cir. 2002).

This Court's review of the dismissal of a counterclaim under Rule 12(b)(6) is plenary and the Court applies the same test as the district court. A counterclaim is properly dismissed when, accepting the well-pleaded allegations as true, the counterclaim plaintiff is not entitled to relief. *Oatway v. Am. Int'l Group, Inc.*, 325 F.3d 184, 187 (3d Cir. 2003); Fed. R. Civ. P. 12(b)(6). In applying this test, the Court must "view the complaint as a whole," must evaluate the well pleaded allegations "in a realistic, rather than a slavish manner," and "need not accept as true 'unsupported conclusions and unwarranted inferences.'" *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 263 n. 13 (3d Cir. 1998).[1]

II.

SMITH & NEPHEW CANNOT CHALLENGE THE JURY'S VERDICT ON VALIDITY BECAUSE IT FAILED TO MOVE FOR JMOL ON VALIDITY BEFORE THE CASE WAS SUBMITTED TO THE JURY

Smith & Nephew did not move for JMOL under Fed. R. Civ. P. Rule 50(a) on validity issues before the district court submitted the case to the jury. Smith & Nephew thereby waived its right to challenge the jury's verdict that the '536 patent was not anticipated and that the Certificate of Correction for the '882 patent was not invalid.

---

[1] Contrary to Smith & Nephew's assertion, *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 919 (3d Cir. 1999), does not mandate that this Court draw "all inferences" in Smith & Nephew's favor.

Rule 50(a) provides that a pre-verdict JMOL motion must "specify the judgment sought and the law and the facts on which the moving party is entitled to judgment." The specificity requirement is applied rigorously. *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1107 (Fed. Cir. 2003) ("a pre-verdict JMOL motion on anticipation is not sufficient to support a post-verdict JMOL on obviousness"); *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1187 (Fed. Cir. 2000) (reversing grant of JMOL where plaintiff moved on some invalidity issues, but "did not make a motion for JMOL on enablement before the case was submitted to the jury"). The purpose of requiring specificity "is to afford the opposing party an opportunity to cure the defects in proof that might otherwise preclude the party from taking the case to the jury." *Duro-Last*, 321 F.3d at 1105. When a party fails to move for JMOL on invalidity before the case is submitted to the jury, it waives its right to challenge a validity verdict on the grounds that it is not supported by substantial evidence. *Jurgens v. McKasy*, 927 F.2d 1552, 1557 (Fed. Cir. 1991).

Here, Smith & Nephew moved for JMOL pre-verdict only on infringement, not invalidity. A15441 (1161:21-1162:2); A14940-72; A15585 (1549:2-5). By failing to move pre-verdict on the validity of the '536 and '882 patents, Smith & Nephew cannot challenge the jury's validity verdict on the

ground that it is not supported by substantial evidence.

Smith & Nephew tries to excuse its failure on the ground that, when Smith & Nephew renewed its JMOL motion on infringement, the district court told Smith & Nephew that "all [its] rights are reserved and my decisions are reserved as well." A15647 (1700). This comment did not mean that Smith & Nephew was free to ignore Rule 50 or the entirety of the Federal Rules of Civil Procedure, as Smith & Nephew suggests. Rather, it meant that Smith & Nephew's rights on issues covered by the JMOL motion it did make were reserved. Any other interpretation of the district court's comment would defeat the purpose of Rule 50(a), because such a vague, all-encompassing reservation of rights would not give ArthroCare notice or opportunity to repair gaps in its proof.

III.

THE JURY REASONABLY CONCLUDED THAT SMITH & NEPHEW FAILED TO PROVE BY CLEAR AND CONVINCING EVIDENCE THAT THE ROOS REFERENCES ANTICIPATE THE ASSERTED CLAIMS OF THE '536 PATENT

Smith & Nephew no longer disputes that its accused products infringe claims 46, 47, and 56 of the '536 patent. The only issue it raises is whether the jury and the district court erred in finding that neither the Roos

Patent nor the Roos Article anticipates the asserted claims. Br. 26.[2]

To establish anticipation, Smith & Nephew had to prove by clear and convincing evidence that a prior art reference disclosed each and every limitation of the asserted claims. *Koito Mfg. Co., Ltd. v. Turn Key Tech., LLC*, 381 F.3d 1142, 1151 (Fed. Cir. 2004); *Vulcan Eng'g Co. v. Fata Aluminum, Inc.*, 278 F.3d 1366, 1373 (Fed. Cir. 2002). Because anticipation is a question of fact, *Koito*, 381 F.3d at 1149, the issue is whether there was substantial evidence from which a reasonable jury could have found that at least one claim limitation was missing from the Roos Patent and the Roos Article.

Here, the record demonstrates that Smith & Nephew failed to meet its heightened burden of proof. The evidence, including the Roos References themselves, the testimony of Smith & Nephew's own expert, and the Patent Office's decision on reexamination that confirmed the patentability of the '536 claims over the Roos Patents, amply supports a finding that the Roos References do not disclose the claimed "electrically conducting fluid supply" or the claimed "connector near the proximal end of the shaft."

A. There Is Substantial Evidence That The Roos References Do Not Disclose "An Electrically Conducting Fluid Supply For Directing Electrically Conducting Fluid"

At the claim construction hearing, Smith & Nephew urged the

[2] Citations to Smith & Nephew's brief are in the form of "Br. [page number]."

district court to construe "electrically conducting fluid" to mean "any fluid that **allows** the passage of electrical current, such as blood and saline." A7549-50 (emphasis added). The district court rejected the broad term "allows" and construed "electrically conducting fluid" to mean "any fluid that **facilitates** the passage of electrical current. Examples of electrically conducting fluid are blood and saline." A18 (emphasis added).[3]

By limiting claim scope to fluids that "facilitate" the passage of electrical current and excluding fluids that merely "allow" current flow, the unchallenged claim construction draws a critical distinction between various types of fluids that are commonly used in electrosurgery.

All fluids used in electrosurgery allow the passage of some electrical current. A15154 (417:13-21). Nonetheless, those skilled in the art classify some of these fluids as electrically "nonconductive" and others as electrically "conductive." Fluids such as glycine and mannitol, which are commonly used in TURP procedures,[4] are considered to be electrically "nonconductive." A15510 (1339:8-14, 1339:19-1340:5). They are so categorized even though they "conduct electricity." A15510 (1339:15-18, 1340:6-10). In contrast, fluids such as blood and saline are classified as

[3] Smith & Nephew does not challenge this construction on appeal.

[4] "TURP" stands for transurethral resection of the prostate.

electrically "conductive" because, unlike their nonconductive counterparts, they are highly conductive. A391 (2:15-16); A393 (6:5-6).

Because even nonconductive fluids conduct electrical current, it was not enough for Smith & Nephew to show that the Roos References disclose fluids that allow current to pass through them. Rather, Smith & Nephew had to show by clear and convincing evidence that the fluid in the fluid supply used in the Roos References **facilitates** the passage of electrical current. This it failed to do.

1. The Roos Patent

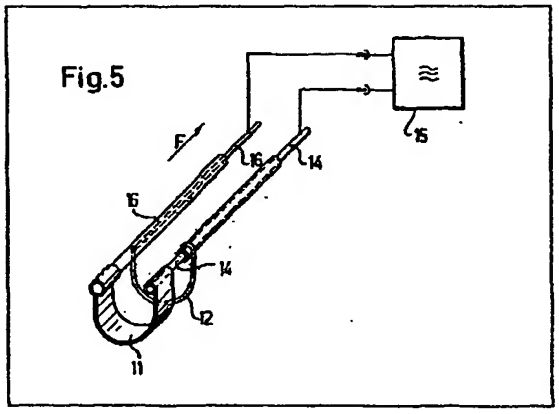
The Roos Patent never describes the fluid supply being used as "electrically conducting fluid." Nor does the Roos Patent ever identify the fluid as saline or Ringer's Lactate. A15511 (1343:10-24). Instead, the Roos Patent refers to the fluid simply as "washing water" or "washing liquid," both of which refer to the same fluid. A15511 (1343:16-1344:6).

The jury heard substantial evidence that the unidentified "washing water" used in the Roos Patent did not "facilitate the passage of electrical current" and was electrically nonconductive.

First, by not distinguishing between the fluid used in monopolar and bipolar electrosurgery, the Roos Patent suggests that the "washing water" was nonconductive. The Roos Patent discusses a conventional monopolar

TURP procedure in which "washing water" is used. A18676 (1:18-61); A15511 (1341:8-1342:3). Smith & Nephew's expert agreed that the monopolar "washing water" must have been an electrically nonconductive fluid, such as glycine. A15511 (1342:15-24). Significantly, when discussing bipolar TURP embodiments – the ones that Smith & Nephew argues anticipate the '536 claims – the Roos Patent describes the fluid used in the same way as the monopolar procedure. A15511 (1343:16-1344:6). From this, the jury was entitled to infer that the same electrically nonconductive fluid that was used in the monopolar procedure was used with the bipolar embodiments.

Second, the Roos Patent's discussion of the bipolar embodiment in Figure 5, depicted below, makes clear that the "washing liquid" was not electrically conductive.



A18674. In describing the electrical connection between the two electrodes during operation, the Roos Patent states that "the neutral electrode 11 in the

form of the steel band rests on the tissue in large-area form, so that good electrical contact is ensured." A18678 (6:51-53). Smith & Nephew's expert admitted that if electrically conducting fluid had been delivered, then there would have been no need for the return electrode to "rest on the tissue" to ensure "good electrical contact" because good electrical contact would have been provided by the electrically conducting fluid. A15512 (1345:10-22).

Third, a subsequent patent issued to Mr. Roos – U.S. Patent No. 4,706,667 ("'667 Patent") (A23658-65) – demonstrates that the Roos Patent delivered electrically nonconducting fluid. The '667 Patent begins by discussing the German parent application (DE OS 2521719) to which the Roos Patent claims priority and Figure 1 of the Roos Patent. *Compare* A23661 (1:14-29) *with* A18671-2, A15516 (1361:4-12, 1363:2-14). The '667 Patent criticizes the Figure 1 embodiment on the ground that the neutral electrode "can only enter into electrical contact with the cutting electrode electrolytically via the secretion which is present during the cutting process." A23661 (1:16-23). Smith & Nephew's expert agreed that if the liquid used with Figure 1 had been electrically conductive when delivered, then tissue secretions would not have been needed to couple the two electrodes; the fluid itself would have done that. A15517 (1365:25-1366:7). If the fluid delivered in the Roos Patent had been electrically conductive, the '667 Patent also would not have said, as it

does, that the fluid was insufficiently conductive to provide "troublefree cutting." A23661 (1:22-25); A15518 (1369:15-24).

The jury also heard evidence that the Patent Office confirmed the patentability of the '536 claims over the Roos Patent in a reexamination. In response to a reexamination request, the Patent Office concluded that the Roos Patent "never describes the use of 'electrically conductive fluid' during electrosurgery." A21882. The Patent Office then reviewed the evidence in detail. A21882-86. On March 14, 2003, the Patent Office issued a Notice of Intent to Issue Ex Parte Reexamination Certificate that confirmed all of the '536 claims. A22232-35. Given this detailed Patent Office review, Smith & Nephew clearly faced a more difficult challenge in proving that the Roos Patent anticipates by clear and convincing evidence. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984); *E.I. du Pont de Nemours & Co. v. Polaroid Graphics Imaging, Inc.*, 706 F. Supp. 1135, 1141 (D. Del.), *aff'd*, 887 F.2d 1095 (Fed. Cir. 1989) (unpublished). The jury reasonably concluded that Smith & Nephew failed.[5]

Smith & Nephew argues that claim 1 of the Roos Patent anticipates because it recites "a space . . . adapted to be filled with liquid to

[5] Contrary to Smith & Nephew's assertion, the district did not "focus" on the Patent Office reexamination in denying Smith & Nephew's JMOL motion. Br. 26 n.5. The district court identified the reexamination as one of many grounds supporting the verdict. A77-79.

provide electrical conductance between said electrodes." Br. 35. This argument ignores the Roos Patent's teaching that electrically nonconductive fluid can provide such conductance. Smith & Nephew's own expert admitted that the "washing water" used in the Roos Patent's monopolar procedure must have been electrically nonconductive fluid. A15511 (1342:15-24). Nonetheless, the Roos Patent states that that electrical current in the monopolar procedure "flows from the cutting loop via the washing water directly to the metal parts of the endoscope shaft located in the washing water." A18676 (1:52-56). Because the Roos Patent teaches that electrically nonconducting fluids "provide electrical conductance," the jury reasonably could have concluded that the phrase "provide electrical conductance" is not a clear and convincing disclosure of fluid that "facilitates the passage of electrical current." Moreover, the phrase "provide electrical conductance" does not establish that the fluid "supply" was electrically conductive fluid at the time it was "directed" to the target site (as the '536 claims require) as opposed to fluid whose conductivity increased after it was delivered to the target site and mixed with conductive tissue secretions, such as blood.

2. The Roos Article

Based on the Roos Article itself and the admissions of Smith & Nephew's expert, the jury reasonably could have found that Smith & Nephew

failed to establish anticipation by clear and convincing evidence.

First, the Roos Article never describes the fluid being delivered as "electrically conducting fluid." Nor does the Roos Article ever identify the fluid as saline or Ringer's Lactate. A15519 (1375:13-21). Instead, it refers to the fluid simply as "irrigation liquid" (*spülwasser*). A18726; A15519 (1375:22-25). Because electrically nonconductive "irrigation liquids" are used in electrosurgery, the jury reasonably could have concluded that "irrigation liquid" is not a clear and convincing disclosure of an electrically conducting fluid supply.

Second, by not distinguishing between the fluid used in monopolar and bipolar electrosurgery, the Roos Article suggests that the "irrigation liquid" was electrically nonconductive. The Roos Article discusses using "irrigation liquid" in a conventional monopolar TURP procedure. A18726; A18726-27 (Fig. 3); A15518-19 (1372:19-1373:7). Smith & Nephew's expert agreed that the monopolar "irrigation liquid" would have been an electrically nonconductive fluid, such as glycine or mannitol. A15519 (1375:3-12, 1376:1-9). When discussing the bipolar TURP embodiments – the allegedly anticipating ones – the Roos Article calls the fluid "irrigation liquid" – exactly the same term it uses in describing the nonconductive monopolar fluid. A18728. Because the fluid is described the same way in both

procedures, the jury was entitled to infer that the same nonconductive fluid was used.

Smith & Nephew argues that the Roos Article discloses electrically conducting fluid because it states that current flows through the "irrigation liquid." Br. 33. This falls far short of the clear and convincing evidence required for anticipation.

To begin with, the Roos Article expressly recognizes that current flow through the "irrigation fluid" does not mean that the fluid is "electrically conducting fluid." The jury heard from Smith & Nephew's own expert that the fluid used in the monopolar procedure (Figure 3) of the Roos Article would have been electrically nonconducting fluid. A15519 (1375:3-12, 1376:1-9). Nonetheless, the Roos Article describes Figure 3 as showing that "the current flows directly from the cutting loop to those parts of the resectoscope projecting into the irrigation liquid" and that the resectoscope shaft is charged electrically "via the irrigation liquid." A18726. Figure 3 itself shows current flux lines extending from the cutting electrode to the metal resectoscope shaft through the nonconductive "irrigation liquid." A18720. This description of current flow through admittedly nonconductive fluid is no different than the language that the Roos Article uses to describe the flow of current through the "irrigation liquid" in the bipolar embodiments. From this, the jury reasonably

could have found that electrically nonconductive fluid was used with the bipolar probes.

Moreover, the Roos Article clearly does not describe an "electrically conducting fluid supply for directing electrically conducting fluid to the target site," as the '536 claims require. Assuming *arguendo* that the Roos Article discloses that electrically conducting fluid was present, which it does not, there is no clear and convincing evidence that the fluid was electrically conducting when it was delivered to the target site, as the claims require, as opposed to becoming more conductive during the cutting procedure. The jury heard testimony about the Roos '667 Patent (*e.g.*, A15517 (1367:13-1368:3), A15518 (1369:15-1370:1)). Given the substantial overlap among the Roos Patent, the Roos Article, and the Roos '667 Patent, the jury reasonably could have inferred that, as described in the Roos '667 Patent, the Roos Article relied upon tissue secretions during surgery to increase the conductivity of electrically nonconductive fluid after it was delivered. A23661 (1:14-29). Using tissue secretions to increase conductivity **after** fluid delivery and **after** the cutting procedure began is fundamentally different than having a "supply" of "electrically conducting fluid" and "directing" that already conductive fluid to the target site.

B. There Is Substantial Evidence That The Roos References Do Not Disclose The Necessary "Connector Near The Proximal End Of The Shaft"

The asserted claims of the '536 patent require a "connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply." The district court construed "connector" to mean "a structure that electrically links the electrode terminal to the high frequency power supply." A17.[6] As demonstrated below, Smith & Nephew failed to prove clearly and convincingly that either the Roos Patent or the Roos Article disclosed a connector located in the claimed position (the proximal end of the shaft) that performed the claimed function (electrically coupling the electrode terminal to the power supply).

1. The Roos Patent

On cross-examination, Smith & Nephew's expert squarely admitted that the Roos Patent does not say where the connector is located. A15518 (1371:1-19). From this admission alone, the jury reasonably could have concluded that the Roos Patent did not disclose a connector near the proximal end of the shaft.

Smith & Nephew argues that a proximal end connector is disclosed by the Roos Patent's reference to "a single cable, 'leading to the rear

[6] Smith & Nephew does not challenge this construction on appeal.

of the endoscope 13.'" Br. 30. The jury reasonably could have rejected this argument based on the admitted evidence. First, Smith & Nephew's expert testified that the Roos Patent "does not say explicitly where the connector is located." A15518 (1371:14-19). Given this admission, the jury reasonably could have found that the "single cable" reference did not describe a connector at the proximal end of the shaft. Second, the jury reasonably could have rejected Smith & Nephew's argument that a "wire" is a "connector." This argument defies common sense: "connectors" connect wires, they are not wires themselves. Indeed, the '536 patent distinguishes between wires (which run from the electrode terminals to the proximal end of the shaft) and connectors (which receive the wires at the proximal end of the shaft and permit coupling to the power supply). A393 (6:31-34) ("The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft."). And Smith & Nephew witnesses, such as Control RF designer Warren Heim, distinguished in their testimony between wires and connectors. A15357 (953:4-8).[7]

[7] Smith & Nephew asserts that the "wires" in the Roos Patent must be a "connector" for purposes of validity because ArthroCare allegedly asserted at trial that the wires near the handle of the accused products were "connectors" for purposes of infringement. Br. 31-32. This claim is incorrect. ArthroCare **never** asserted that the "connector" limitation read on mere wires in the

2. The Roos Article

Smith & Nephew failed to show by clear and convincing evidence that the fitting at the proximal end of the device shown in Figure 9 of the Roos Article is "a structure that electrically links the electrode terminal to the high frequency power supply," as the unchallenged claim construction requires. A17.

The Roos Article never calls the fitting a "connector" and never discusses its function. A18725-733. At trial, Smith & Nephew relied solely on Figure 9 and the unsupported testimony of its expert to prove that the fitting met the requirements of the claimed connector. Smith & Nephew's expert did nothing more than testify in conclusionary fashion that the fitting was a connector. A15500 (1298:17-23). But he did not explain the basis for his opinion and he never offered any testimony that the connector performed the required function of electrically linking the electrode terminal to the high frequency power supply. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1570 (Fed. Cir. 1986) (a jury "may reach a conclusion that a patent remains valid *solely* on the failure of the patent challenger's evidence to

---

accused products. Rather, ArthroCare identified specific non-wire structures that constitute the "connectors": a resistance weld between the cable and the shaft for the Saphyre (A22787-22802); the "connector clamp" of the Control RF (A22544-22548); and the "outer blade contact" for the ElectroBlade (A22687). ArthroCare's positions on infringement and validity are entirely consistent.

convincingly establish the contrary"). Because the resectoscope includes an optical system and delivers "irrigation liquid," the jury reasonably could have inferred that the function of the fitting related to fluid delivery or optics rather than "electrically linking" the electrode terminal to the high frequency power supply.

The jury also could have chosen not to believe Smith & Nephew's expert, Dr. Taylor, as his credibility had been impeached on cross-examination. For example, the jury learned that Smith & Nephew's expert was not independent; that he refused to answer questions during his deposition based on his attorney-client relationship with Smith & Nephew's attorneys; that he changed his deposition testimony after consulting Smith & Nephew's counsel; and that his testimony at trial that claim 1 of the Roos Patent (and its limitation that the neutral electrode be located "within said endoscope body") covered the Figure 7 and 8 embodiments was contradicted by his sworn expert report and his original sworn deposition testimony that Roos Patent claim 1 did not cover Figures 7 and 8 (and that their neutral electrode was not within the endoscope). A15513-15 (1351:7-1353:17, 1354:18-1358:4). Dr. Taylor's trial testimony regarding critical aspects of another alleged prior art reference also contradicted his sworn deposition testimony. A15521-22 (1382:2-1386:1). Accordingly, the jury was free to disregard Dr. Taylor's testimony as lacking in

credibility. *U.S. Philips Corp. v. Windmere Corp.*, 861 F.2d 695, 704 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1068 (1989) ("The jury was not required to accept his expert testimony, even if it was uncontradicted."); *Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 183 (Fed. Cir. 1994) ("It is within the province of the jury to determine the credibility of a witness and ... the jury is not required to accept testimony as true, even if it is uncontradicted").

IV.

SUBSTANTIAL EVIDENCE SUPPORTED THE JURY'S VERDICT THAT SMITH & NEPHEW INFRINGED THE '592 PATENT

The jury found that Smith & Nephew infringed all of the asserted claims of the '592 patent. A21; A374-375. Smith & Nephew does not challenge the district court's claim construction or the district court's jury instructions on infringement. Thus, the only question is whether there was substantial evidence from which a reasonable jury could find that the use of Smith & Nephew's accused products practiced the claim methods. As demonstrated below, the admissions of Smith & Nephew's witnesses, the admissions in Smith & Nephew's documents, and the testimony of ArthroCare's expert witness provided the jury with overwhelming proof of infringement under the district court's unchallenged claim construction. Smith & Nephew's attacks are based on a facially flawed reading of the unchallenged

claim construction, inaccurate statements about the ArthroCare patents, and a flawed review of the evidence.

A. Under The Unchallenged Claim Construction, The Evidence Convincingly Established Infringement

As the claim preambles state, the '592 patent claims are methods for "applying electrical energy to a target site" on or in a patient's body.[8] The method is accomplished when the three claimed steps – (1) positioning an active electrode near a target site in the presence of electrically conductive fluid, (2) positioning a return electrode in the fluid so it is not in contact with or spaced away from the body structure, and (3) applying a high frequency voltage so that current flows in a path between the electrodes and through the fluid – are performed together. A465-466 (24:6-8, 25:42-44).

It was undisputed that Smith & Nephew's Saphyre, ElectroBlade, and Control RF products had to be used with electrically conducting fluid; that the active electrode was positioned close to target tissue in the presence of electrically conducting fluid; that the return electrode was positioned in electrically conducting fluid; and that a high frequency voltage caused electrical current to flow in a path between the two electrodes through the electrically conducting fluid. A22613; A22647, A22649; A22678; A23173,

[8] The methods are not methods "of performing a surgical procedure," as Smith & Nephew incorrectly suggests. Br. 12.

A23202; A15154-57 (418:17-427:13); A15209-15210 (551:15-556:9); A15211-15212 (560:1-561:10). Smith & Nephew's **sole** noninfringement argument was that ArthroCare had not shown that the methods were performed while the return electrode was "not in contact" with tissue.

The district court gave the jury the following instruction on the meaning of the "not in contact" limitation:

> The claim limitation the return electrode not in contact with the body structure is clear -- the return electrode is not to contact the body at all during the performance of the claimed method. The claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps of the claim has been completed.

A15652 (1718:19-25). The district court also instructed the jury on imperfect infringement:

> With respect to the asserted claims of the '592 and '882 patents, the accused methods need not always practice the invention of any asserted method claim, so long as ArthroCare has proven by a preponderance of the evidence that the accused methods operate in a way that meet each and every step of the method described in the claim some of the time.

A15651 (1716:7-13). Both separately and together, these instructions make two things clear. First, the '592 methods are infringed even if the three claim steps are performed together only for a short time. Because the claims contain no time limitation, there is infringement if the three steps are performed

together for one second, for three seconds, for five seconds, or for any other length of time. Second, using the accused products in a way that does not infringe some of the time does not negate earlier or later uses that do infringe. If the three claim steps are performed together for five seconds, and then in the sixth second the return electrode contacts tissue, the contact in the sixth second does not negate the infringement that occurred over the previous five seconds.

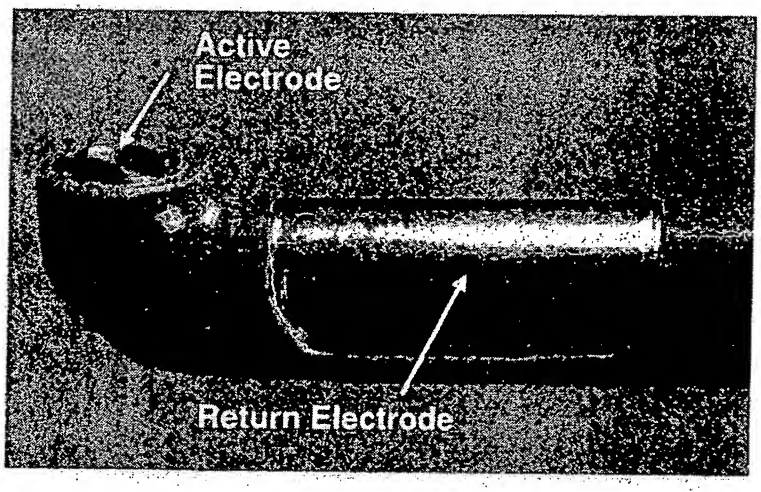
Significantly, Smith & Nephew does not challenge either of these instructions on appeal. It does not contend that the "no time limitations" charge was in error. It does not contend that later acts of noninfringement negate earlier acts of infringement. Thus, the question is whether there was substantial evidence from which a reasonable jury could find that the accused products were used at times to perform the three claim steps together. The answer to that question is a resounding yes.

1. Product Design

The jury was entitled to infer that all three method steps were performed together, including the "not in contact" step, from evidence that the accused products were designed to be used so that the return electrode did not contact tissue. A15149 (396:14-398:12); A15156-15157 (424:8-427:13). For all three probes, the active electrode was designed to serve as the tissue treatment electrode. A15149 (396:14-397:1), A15151 (404:22-405:5);

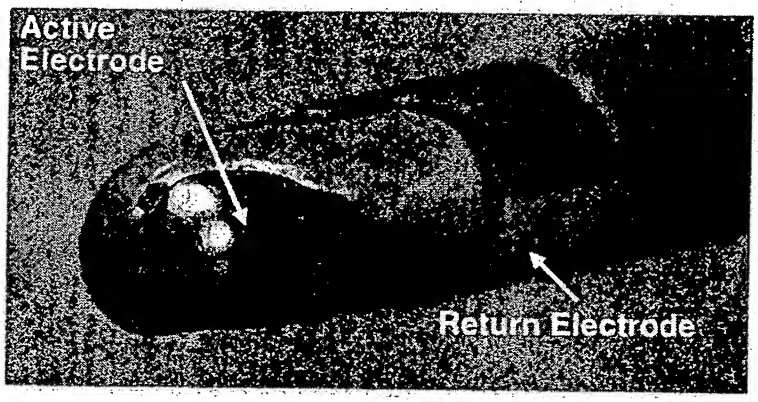
The Accused Products

Saphyre



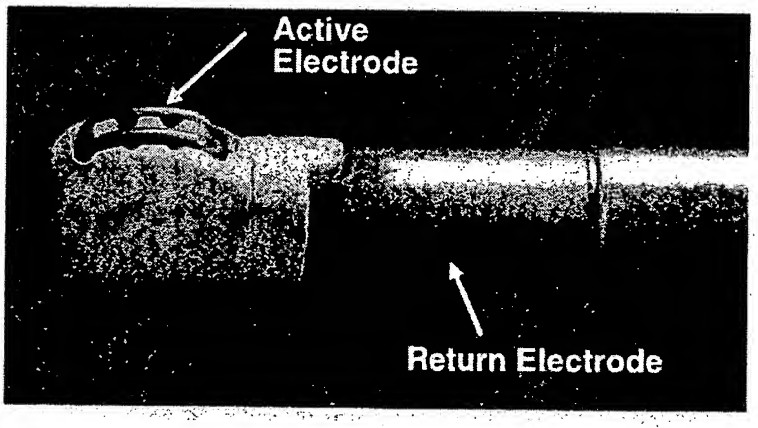
A26874.

ElectroBlade



A26869.

Control RF



A26876.

A22851-52; A22647; A22649. As shown on the facing page, the active electrode for all three accused products is positioned at the extreme distal end of the probe. In contrast, the return electrode is spaced axially (up the shaft) from the active electrode, away from where the active electrode contacts target tissue. In the case of the Saphyre and Control RF, the return electrodes also are on a plane that is recessed from the active electrode, which further removes the return electrode from the tissue being treated. A15149 (397:14-22), A15151 (405:15-18), A15153 (412:6-12).

Dr. Goldberg, an electrosurgery expert, testified in detail how these designs meant that, during use, the return electrode of the accused products would not be in contact with tissue for periods of time while the other claim steps were being performed. A15154-15157 (418:17-427:13).

Smith & Nephew's witnesses, including Warren Heim and Joan McCreary, confirmed that the accused products were designed so that the return electrode would not contact tissue during use. A15217 (581:19-582:6); A15209-15210 (551:15-555:11). A Saphyre design drawing shows how the axial, recessed placement of the return electrode avoids tissue contact during use:

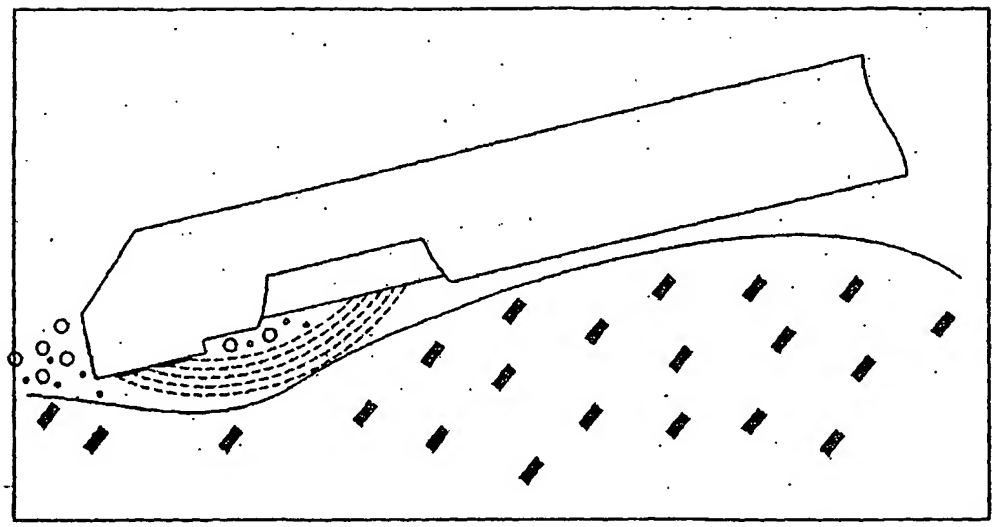


Fig. 2: Saphyre Design History File. A22778.

2. Instructions for Use

The jury reasonably could have found that the return electrode did not contact tissue while the other claim steps were performed based on Smith & Nephew's instructions to doctors. A69. For example, Smith & Nephew's Saphyre Sales Guide warns that "[c]are should be taken to prevent tissue contact with the return electrode on the Saphyre probe shaft." A23202 (emphasis added). Another Smith & Nephew document titled "Competitive Selling ArthroCare" tells doctors to "keep the [active] electrode" of the Saphyre "level with the target tissue" during use. A22836 As the document illustrates, when the active electrode is held level, contact between the axially spaced return electrode and tissue is avoided. A22841.

Similarly, Smith & Nephew's Sales Training CD for the ElectroBlade instructs users to "[e]nsure the entire tip including the return

[electrode] is immersed in saline," to "[p]resent" the active electrode (not the return electrode) to the tissue, and to "use suction to pull bleeding tissue to the blade for coagulation." A22649; A22653. Because the ElectroBlade's return electrode is positioned axially from and behind the active electrode, when the return electrode is immersed in saline and the tissue is pulled toward the active electrode, the return electrode will not be in contact with tissue.

Smith & Nephew's Control RF "Instructions for Use" likewise instruct doctors to be sure that the return electrode is "completely surrounded" by electrically conducting fluid during use. A22678. The return electrode cannot both be "completely surrounded" by fluid and in contact with tissue.

3. Use

The jury had evidence from Smith & Nephew's witnesses and videotapes which showed that the return electrode is not in contact with tissue at times when all the other claim limitations are performed.

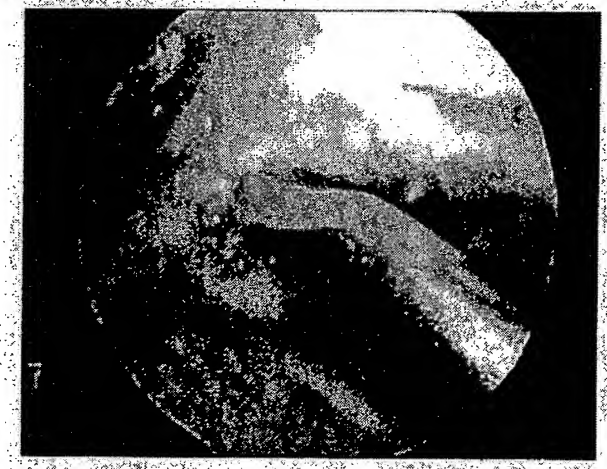
One of Smith & Nephew's experts, Dr. Michael Choti, testified that, for each accused product, when the active electrode is positioned near the target site and energy is being applied, there are times when the return electrode is not in contact with tissue:

> Q: And when you tested the Saphyre device inside the joint space, while you were applying energy, there were points in time when the return electrode was not in contact with tissue?

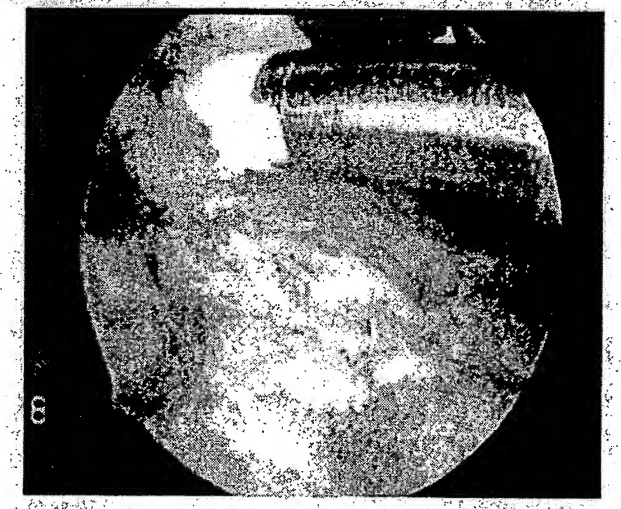
Dr. Choti's Video (PX 105)

Saphyre

ElectroBlade



Control RF



A26890

A: That's correct.

Q: When you used the ElectroBlade and you applied energy, there were points in time when the return electrode of the ElectroBlade was not in contact with tissue?

A: During some points in time, yes.

Q: And when you used the Control RF product, and you energized it, there are points in time where the return electrode was not in contact with tissue?

A: That's correct.

* * *

Q: So there were points in time where energy was applied with all these devices and there was no contact between the return and the tissue?

A: Yes.

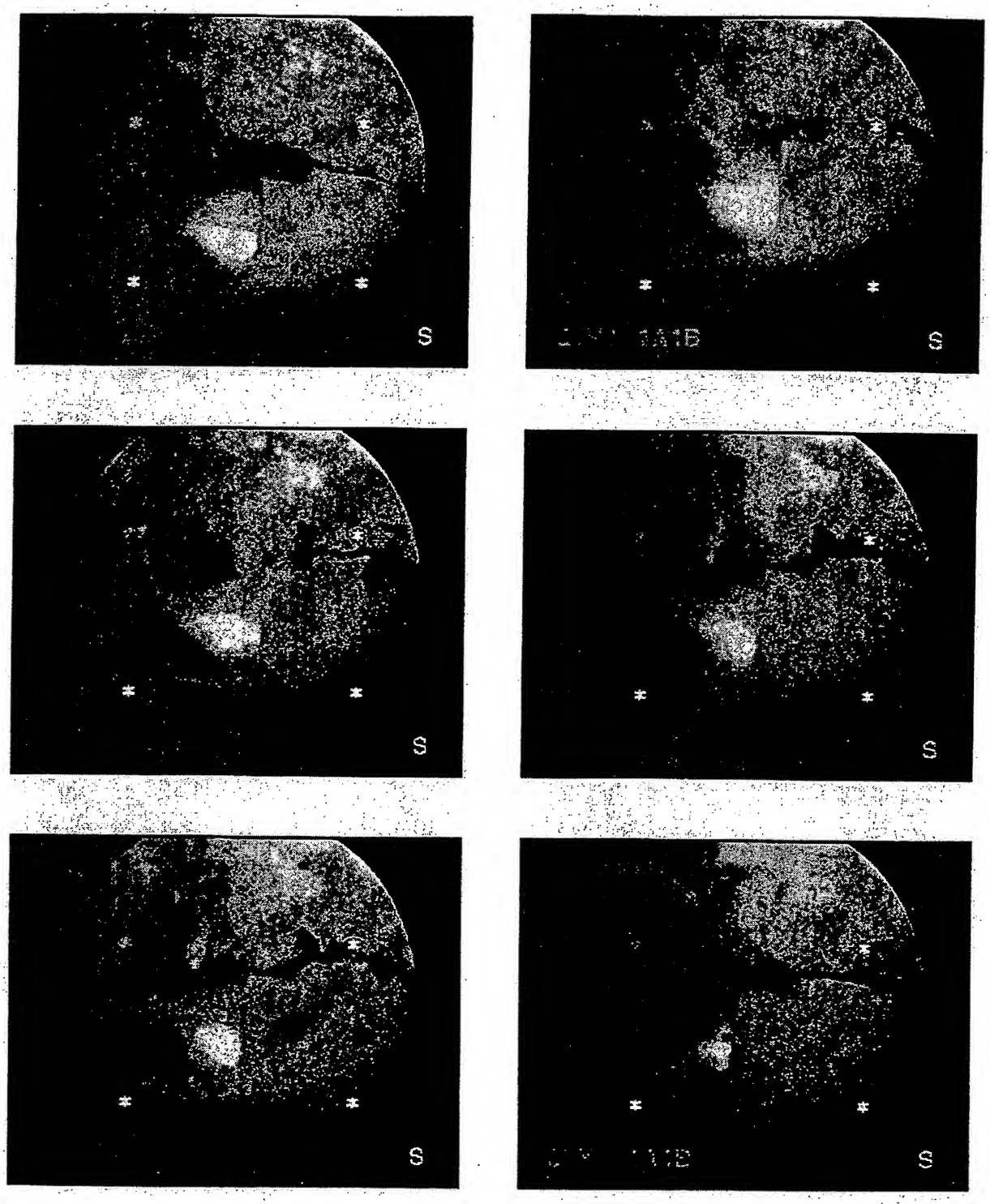
A68; A15257 (743:7-744:12); A15252 (724:11-725:17).

The jury observed extended videotape segments of Dr. Choti using the accused products to apply energy to tissue in electrically conductive fluid. A26890. The videotapes showed the accused products performing the complete method for substantial periods of time: the active electrode is near tissue and in the presence of electrically conducting fluid, the return electrode is in the fluid and is not in contact with tissue, and energy is applied so that current flows between the two electrodes. Still images from the videotape (facing page) confirm this.[9]

In addition, a Smith & Nephew videotape that was used to train its

[9] Smith & Nephew concedes that in these stills, the "presence of an orange glow, bubbles, or charring indicates that energy is being applied." Br. 51.

Saphyre Sales Training Video (DTX-315)



A26891

salesforce on product use shows that the Saphyre's return electrode is not in contact with tissue for substantial periods while the other claim steps are being performed (facing page). A26891; A19249-19253; A15361 (967:13-24). Both the ElectroBlade project manager, Karen Drucker, and the Saphyre project manager, Kate Knudsen, admitted that there are times when the return electrodes of the Saphyre and ElectroBlade are not in contact with tissue and energy is being applied. A15397 (985:2-13); A15409 (1036:3-25).

As Dr. Goldberg testified, the use of the accused products infringes the asserted claims of the '592 patent because there are times during their use when the return electrode is not in contact with tissue and the other claim limitations are being performed. A15154-15157 (418:17-427:13). That is all that the unchallenged claim construction requires.[10]

B. Smith & Nephew's Arguments Are Based On A Fundamental Misreading Of The Unchallenged Claim Construction And The Intrinsic Evidence

Smith & Nephew principal argument is that the jury "disregarded" the district court's construction of the "not in contact" limitation. According to Smith & Nephew, the claimed methods are not infringed if the return electrode

[10] Should the Court determine that a reasonable jury could not have found literal infringement, ArthroCare requests that the Court remand for further proceedings, as the district court erred in not allowing ArthroCare to put on evidence of infringement under the doctrine of equivalents. A15157 (430:7-431:5); A15409 (1034:4-1035:16); A15433-36 (1131:14-1144:21).

is not in contact with tissue for only a short period of time. Br. 48-49. This argument, which directly contradicts the unchallenged claim construction, was rejected by the district court. This Court should reject it too.

During the claim construction hearing, Smith & Nephew argued that the "not in contact" language required that "the return electrode must be kept away from, and not allowed to touch any portion of the body structure during the surgery." A7587, A7598.[11] The district court rejected this construction, because "during the surgery" would have imposed an unclaimed temporal requirement on the length of the method. Before trial, in ruling on summary judgment motions, the district court explained that "[t]he claim limitation in dispute has no relation to the time required to perform the method." A14063-64. The district court then emphasized that "[t]he claimed method does not contain any time limitations. Thus, the claimed method is performed when each of the three steps of claim 1 has been completed." A14064.

The district court made clear in her summary judgment ruling that, because the claim included no time limitation, performing the method even for a short period of time constitutes infringement:

[11] Smith & Nephew's assertion about ArthroCare's requested claim construction is false. Br. 48. As the joint claim construction statement shows, ArthroCare argued that the "not in contact" limitation "is clear and no further construction is needed." A7587, A7598.

> [Smith & Nephew] does not dispute that, at times during the surgery, the return electrode of the accused product is not in contact with the body structure and each of the three steps of the claimed method are performed. The court, therefore, finds that the use of the Saphyre product literally infringes claim 1 of the '592 patent.

A14064. This ruling also was consistent with the law of imperfect infringement, which provides that "an accused product that sometimes, but not always, embodies a claimed method nonetheless infringes." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 622-23 (Fed. Cir. 1995).

The district court's instruction to the jury on the "not in contact" limitation was exactly the same as the construction she applied on summary judgment. A15652 (1718:16-25).[12] Because Smith & Nephew does not challenge the construction, and because the construction means that infringement "at times" is nonetheless infringement, Smith & Nephew's argument cannot stand.[13]

Smith & Nephew appears to argue that the use of its products does

---

[12] Smith & Nephew's suggestion that the district court's construction somehow changed is wrong. Br. 46 n.12.

[13] At all events, as demonstrated above, the evidence (including videotapes and testimony) shows that there were not merely "sporadic breaks in contact," but rather that there were substantial periods of time during which the return electrode of each accused product was not in contact with tissue and the other claim steps were being performed.

not infringe because they have large exposed return electrodes that will contact tissue whereas the '592 patent allegedly teaches to avoid all tissue contact by covering the return electrode with insulation. Br. 49, 53-54. This contention is both irrelevant and wrong. It is irrelevant because accused products do not infringe preferred embodiments; they infringe claims. The argument is wrong because the '592 patent teaches how to position a large area exposed return electrode so as to minimize tissue contact. For example, the '536 patent (which is incorporated by reference in the '592 patent) discloses several embodiments (such as Figure 16) in which a large, annular return electrode (56) is exposed and spaced away from the tissue treating active electrodes (58):

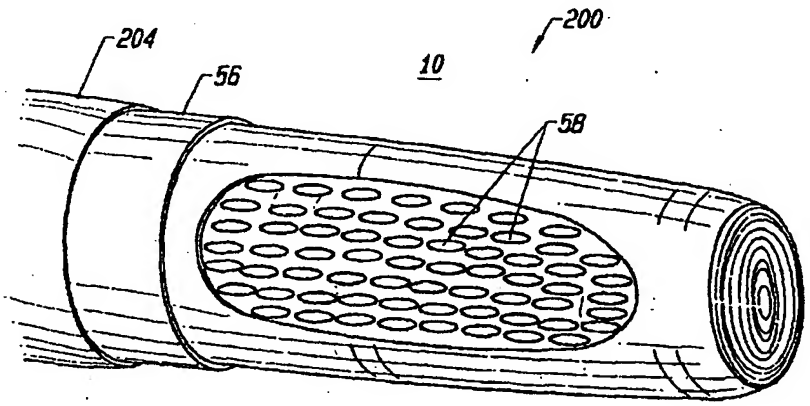


FIG. 16

The '592 patent also teaches that return electrode contact with tissue can be minimized by positioning the return electrode axially from the active

electrodes. A392 (3:60-62); A463 (19:40-45).

Smith & Nephew's assertion that the prosecution history of the '592 patent supports noninfringement is similarly misplaced. Br. 50. Nothing in the file history changes the district court's clear claim construction – a construction which Smith & Nephew does not challenge and which the district court already held covers the use of devices in which the return electrode is not in contact with tissue "at times." Moreover, Smith & Nephew's argument misstates the file history. During prosecution, the Applicants distinguished their invention from prior art devices in which the return electrode must always be in contact with tissue to work. A20541-20542; A20556. In their January 24, 2000 amendment, the Applicants argued that the Baker, Lax, Abele, and Knowlton references required contact between the return electrode and tissue in order to work:

> As stated in col. 3, lines 58-63 and col. 6, lines 63-66 of Baker, the return electrode must function as a grounding pad and thus is in contact with the tissue. . . . In the Abele device, the electrodes are designed to press again[st] the heart tissue with the desired contact pressure. Similarly, the Lax device must have contact between both the active and return electrodes and the patient's tissue. . . . In the Knowlton device . . . the return electrode must be in contact with the tissue in order for the RF power to be transferred thereto.

A20541-20542. Distinguishing prior art devices that only work when the return electrode is in contact with tissue does not disclaim coverage of devices

that work without tissue contact but which sometimes contact tissue.

V.

THE JURY REASONABLY CONCLUDED THAT SMITH & NEPHEW DID NOT MEET ITS BURDEN OF PROVING BY CLEAR AND CONVINCING EVIDENCE THAT THE '882 CERTIFICATE OF CORRECTION IS INVALID

At trial, Smith & Nephew did not contest that its accused products infringe the asserted claims of the '882 patent as corrected by the Certificate of Correction. Smith & Nephew's entire noninfringement case was based on its argument that the Certificate is invalid.

To establish invalidity, Smith & Nephew had to prove by clear and convincing evidence that one skilled in the art would not recognize the errors in the originally issued claim or know how to correct them in light of the patent and its prosecution history. *Superior Fireplace Co. v. Majestic Prods. Co.*, 270 F.3d 1358, 1370, 1372 (Fed. Cir. 2001). This heightened burden applied because certificates of correction are presumed valid. *Id.* (1367 n.1); *Winbond Elecs. Corp. v. Int'l Trade Comm'n*, 262 F.3d 1363, 1371 (Fed. Cir. 2001).

The record amply demonstrates that Smith & Nephew utterly failed to carry its burden of proof at trial and that substantial evidence[14]

---

[14] Smith & Nephew asserts that the jury verdict should be reviewed without deference (Br. 58 n.19), but provides no support for this standard.

supported the jury's (and the court's) validity finding.[15]

A. The Evidence At Trial Confirmed The Certificate Of Correction's Validity

The relevant inquiry under *Superior Fireplace* is how one of ordinary skill in the art would interpret the claims in light of the specification and prosecution history, as Smith & Nephew acknowledged at trial.[16]

Notwithstanding its heightened burden of proof, Smith & Nephew did not present any evidence to show how one skilled in the art would interpret the error in original claim 1 of the '882 patent or how one would correct it. Indeed, Smith & Nephew elected not to have any of its three technical experts address the issue.[17]

Superior Fireplace does not suggest that a validity finding should be reviewed without deference. Moreover, *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc), is a claim construction case that has nothing to do with the validity of certificates of correction.

[15] The district court agreed with the jury and independently concluded that "the certificate of correction is valid." A100.

[16] Smith & Nephew told the district court that "[t]he Superior Fireplace test says that the standard is what a person of ordinary skill in the art would read the claim as, what they know, if there was a correction that needed to be made and would they know how to make that correction." A15354. The district court concurred. A15491.

[17] At trial, Smith & Nephew made a last-ditch attempt to have one of its fact witnesses, Warren Heim, offer an expert opinion as to what one skilled in the art would have understood about the uncorrected claims. The district court properly precluded Mr. Heim from providing such expert testimony because Smith & Nephew failed to identify him as an expert and had unfairly blocked ArthroCare from discovering the subject matter of his expected trial testimony

Instead, the evidence confirmed that claim 1 was properly corrected to fix typographical errors. The main evidence of this was the prosecution history itself. The jury and district court also heard the testimony of John Raffle, the prosecuting attorney.[18]

ArthroCare filed application claim 23, which eventually issued as claim 1, on November 22, 1995. A21275; A21318-21319. As filed, claim 23 claims a method that is performed using two electrodes – an "active electrode" and a "return electrode." *Id.* Following a restriction requirement, ArthroCare amended the elected claims, including claim 23, on February 19, 1997, "to more clearly define the relationship between the active and return electrodes and the high frequency voltage source." A21362-65. As amended, application claim 23 continued to recite only two electrodes – an "active electrode" and a "return electrode." A21363. It used the phrase "active electrode" four times, in each case referring to the same electrode.

Shortly thereafter, and still before any examination by the Patent Office on the merits, ArthroCare filed a supplemental amendment on March 25, 1997. A21471-72. That amendment changed application claim 23 to read:

---

at his deposition. A15354-55; A58-59.

[18] Smith & Nephew offers no support for its position that it was improper for the jury or the court to consider Mr. Raffle's testimony. Br. 61 n.21. Indeed, the fact that Smith & Nephew itself called Mr. Raffle on the topic belies its argument.

> 23. (Twice Amended) A method for applying energy to a target site on a patient body structure comprising:
>
> providing an [active] electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
>
> positioning the active electrode in close proximity to the target site in the presence of an electrically conducting terminal [liquid]; and
>
> applying a high frequency voltage between the [active] electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid [liquid] in a thin layer over at least a portion of the [active] electrode terminal and to induce the discharge of energy to the target site in contract with [from] the vapor layer.

A21472. In making these amendments, ArthroCare advised the Patent Office that it had "prepared a few minor amendments" to the claims. A21482.

Reading the supplemental amendment together with the original and first amended versions of application claim 23 makes clear that ArthroCare made two typographical errors in amending claim 23. *Compare* A21363 *with* A21472. The first clerical error involved the phrase "active electrode." Before the supplemental amendment, application claim 23 used the phrase "active electrode" four times. A21363. In supplementally amending the claim, ArthroCare changed the first, third, and fourth mentions of "active electrode" to "electrode terminal," but failed to change the second. A21472. As a result, application claim 23 included a reference to "the active electrode" in line 6,

even though the phrase "an active electrode" no longer appeared earlier or later in the claim. *Id.* Before the supplemental amendment, the first, second, third, and fourth mentions of "active electrode" all plainly referred to the same electrode. A21363. The Certificate of Correction merely changed "the active electrode" to "the electrode terminal." A18634. Clearly, it was reasonable for the jury and the district court to find that the correction was not improper.

The second clerical error involved the phrase "electrically conducting liquid." In the supplemental amendment, the word "liquid" in the phrase "electrically conducting liquid" was changed to "terminal" so that the claim recited an "electrically conducting terminal." A21472. Again, this plainly was a clerical error, as the phrase "electrically conducting terminal" did not appear anywhere in the patent application and the word "liquid" was changed to "fluid" elsewhere in claim 23. *Id.* The Certificate of Correction changed "terminal" to "fluid." A21655.[19]

The testimony at trial confirmed the clerical, inadvertent nature of these errors. Mr. Raffle testified that in drafting the March 25, 1997 amendment (A417), he intended "to make a global amendment" to change "active electrode" to "electrode terminal" every time it appeared in the pending claims. A15578 (1524:1-20). He explained that the failure to change the

[19] On this appeal, Smith & Nephew does not dispute that this correction was proper.

phrase "active electrode" to "electrode terminal" was a "mistake." A15578-79 (1524:25-1525:11). Mr. Raffle also intended to replace the term "electrically conducting liquid" with "electrically conducting fluid" throughout the claims, but one time he inadvertently changed "liquid" to "terminal" instead of "fluid" *Id.* (1524:14-20, 1525:12-19). Mr. Raffle recognized that he had made clerical errors the very day that the patent issued and he requested a Certificate of Correction the next day. A15579 (1526:14-1527:19).

The Request for Certificate of Correction, also part of the prosecution history, confirms that Mr. Raffle made a typographical error. A21506. It explains what is obvious from the rest of the prosecution history: "Applicant mistakenly forgot to replace the term 'active electrode' with 'electrode terminal' on line 5." *Id.* The Examiner reviewed the Request and concluded that the requested change would not "constitute new matter or require reexamination of the application" and would not "materially affect the scope or meaning of the claims allowed by the examiner in the patent." A21509.

This record overwhelmingly supports the jury's verdict that the Certificate of Correction was not invalid because the clerical errors, and their remedy, were clear.

B. Because Smith & Nephew's Arguments Are Inconsistent With Claim 1 As Issued, The Patent Specification, And Its Prosecution History, They Should Be Rejected

Smith & Nephew argues that the certificate correcting "the active electrode" to "the electrode terminal" in claim 1 is invalid based on its assertion that another correction – changing "the active electrode" to "an active electrode" – is the "most natural correction." Br. 61. Calling this correction the "most natural" is ironic, because Smith & Nephew never once thought to raise this argument below – not on summary judgment, not at trial, and not in post-trial motions. As demonstrated below, Smith & Nephew's newly minted position in no way constitutes clear and convincing evidence of invalidity. Not only would Smith & Nephew's construction make claim 1 nonsensical, but it finds no support in the specification or file history.

As a threshold matter, Smith & Nephew's argument is based on the unsupported premise that "an electrode terminal" and "the active electrode" in uncorrected claim 1 refer to two different electrodes and that the Certificate of Correction broadened claim 1 by not requiring this "third" electrode. Br. 60.[20] In fact, the evidence shows that "the active electrode" and "an electrode

[20] Although Smith & Nephew suggests that the corrections were an attempt to reduce the required number of electrodes from three to two and thereby "ensnare its competitors' products" (Br. 61), there was no evidence to support that. The jury was entitled to credit Mr. Raffle's testimony that these typographical errors were inadvertent. The district court, which had the

terminal" in uncorrected claim 1 refer to the same electrode and that changing "the active electrode" to "the electrode terminal" did not change the number of required electrodes. The only witness who testified on the subject – Dr. Nahum Goldberg of Harvard Medical School and an expert in the design and use of electrosurgical devices – testified that the phrase "the active electrode" was a reference "that's going back to" the "electrode terminal." A15429 (1112:23-1113:8).[21] Moreover, the district court construed "electrode terminal" to mean "one or more active electrodes," which makes clear that an active electrode can constitute an electrode terminal. A14899.[22] From this, the jury was entitled to conclude that "the active electrode" in uncorrected claim 1 finds its antecedent in "an electrode terminal" and that this correction did not reduce the number of required electrodes. Smith & Nephew's new argument, which finds no support in the evidence at trial, should be rejected. *Great N. Corp. v. Henry Molded Prods., Inc.*, 94 F.3d 1569, 1573 (Fed. Cir. 1996) ("The time to prove that diamonds are routine was with evidence at trial, not with lawyer's argument in the appeal brief.").

---

opportunity to assess the credibility of ArthroCare's witnesses, concluded that ArthroCare "made honest mistakes in amending the claims" and "did not craft claims" to read on competitor products. A84.

[21] As this shows, Dr. Goldberg never testified that corrected claim 1 was broader because the correction eliminated "the active electrode" from the claim, contrary to Smith & Nephew's suggestion (Br. 60).

[22] Smith & Nephew does not challenge this construction on appeal.

Smith & Nephew's argument also fails because there is nothing in the intrinsic record which suggests that one of ordinary skill would have changed "the active electrode" to "an active electrode."

First, Smith & Nephew's "most natural correction" makes no sense in the context of claim 1. If Smith & Nephew's correction were made, claim 1 would read as follows:

> 1. A method for applying energy to a target site on a patient body structure comprising:
>
> providing an electrode terminal and a return electrode electrically coupled to a high frequency voltage source;
>
> positioning an active electrode in close proximity to the target site in the presence of an electrically conducting fluid; and
>
> applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

Under this formulation, the electrode terminal and the return electrode would be coupled to the high frequency voltage source, but the separate active electrode would not be, even though it would be in close proximity to the target site and would be in contact with electrically conducting fluid. Smith & Nephew does not explain what the point would be of

positioning the active electrode in close proximity to the target site in electrically conducting fluid when it would not be coupled to a voltage source and would not have any effect on the fluid or the target site. Nor does Smith & Nephew explain why a voltage sufficient to vaporize a thin layer of fluid to discharge energy to the target site would be applied between the electrode terminal and the return electrode when it is the active electrode, not the electrode terminal, that is positioned in the fluid near the target site. Smith & Nephew does not point to any description in the patent of a device that operates in this manner. Put simply, Smith & Nephew's proposed correction renders claim 1 nonsensical.

Second, the '882 patent specification undermines Smith & Nephew's position. The specification never uses "active electrode" to describe a different electrode than an "electrode terminal," which is what Smith & Nephew's proposed correction would do. The specification does not describe any embodiment in which one electrode is called "an active electrode" and a different electrode is called "an electrode terminal." Instead, the terms "electrode terminal" and "active electrode" are used to refer to the same electrodes throughout the specification. For instance, in describing the embodiment depicted in Figures 21 and 22, the specification refers to element 58 interchangeably as "electrode terminal" and "active electrode." A18629

(*Compare* 20:52-55 *with* 20:36-38).

Finally, the prosecution history does not support Smith & Nephew's "most natural correction." Smith & Nephew's argument assumes that the purpose of the March 25, 1997 supplemental amendment was to narrow application claim 23 substantially by requiring a third electrode above and beyond the "electrode terminal" and the "return electrode." But the file history directly contradicts this assumption. From the beginning, application claim 23 was written as a two electrode claim. It was filed as a two electrode claim in November 1995 and it was first amended as a two electrode claim in February 1997. At the time of the supplemental amendment, the Patent Office had not rejected the claim and had not examined it on the merits. Given this posture, there was no need or reason for ArthroCare to narrow the claim substantially by requiring a third electrode. Moreover, in filing the supplemental amendment, ArthroCare told the Patent Office that it was making "a few minor amendments." Requiring a third, different electrode would not be a "minor amendment."

For the first time on appeal, Smith & Nephew argues that its "most natural correction" is correct because it is the only correction that "solves" a purported antecedent basis problem with dependent claim 53. Br. 61. Claim 53 recites "the active electrode." Claim 53 depends from claim 52,

which in turn depends from claim 1 or 28. A18633 (28:9-11). Corrected claim 1 recites only an "electrode terminal," not "an active electrode." According to Smith & Nephew, if "the active electrode" in claim 1 were changed to "an active electrode," claim 53's antecedent basis issue would vanish. What Smith & Nephew ignores is that claim 28 (like corrected claim 1) does not recite "an active electrode" either, but was amended in March 1997 to recite only an "electrode terminal." A21476. If Smith & Nephew's "most natural correction" were made, claim 53 still would have an antecedent basis issue because claim 28 does not recite "an active electrode."[23] What this evidence really shows is that the intrinsic record uses "electrode terminal" and "active electrode" to describe the same electrodes, not different electrodes.[24]

---

[23] Smith & Nephew assertion that corrected claim 1 renders dependent claim 53 invalid for indefiniteness finds no support in the record. Br. 61, 63. As Dr. Goldberg's testimony and the district court's claim construction made clear, "the active electrode" in claim 53 would have been understood by one skilled in the art to find antecedent basis in claim 1's "an electrode terminal." A15428-29 (1112:23-1113:8), A15432 (1126:18-22); *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1117 (Fed. Cir. 1987) ("The missing antecedent clause...did not fail to 'inform the public during the life of the ['274] patent of the limits of the monopoly asserted.'") (citation omitted).

[24] Smith & Nephew also asserts that ArthroCare intentionally left "the active electrode" in application claim 23 to limit the claim to embodiments with two or more active electrodes. Br. 62. This ignores the fact that claim 2, which depends from claim 1, is limited to embodiments with two or more electrode terminals. A18631 (24:18-21). Plainly, claim 1 was drafted to cover embodiments with one or more electrode terminals and claim 2 was drafted to claim embodiments with two or more electrode terminals.

VI.

THE DISTRICT COURT PROPERLY DISMISSED SMITH & NEPHEW'S "SHAM LITIGATION" COUNTERCLAIM

Smith & Nephew's antitrust counterclaim was a textbook "sham litigation" pleading. The thrust of the counterclaim was that ArthroCare brought this lawsuit against Smith & Nephew even though ArthroCare and Ethicon allegedly knew that the patents-in-suit were invalid. Because ArthroCare prevailed on all issues at trial, including validity, Smith & Nephew could not have prevailed on this counterclaim as a matter of law and the district court properly dismissed it. Smith & Nephew's appeal theory is based on unpleaded assertions about unpleaded conspiracies that are based on unpleaded contract provisions, and cannot save the counterclaim from dismissal.

A. Under *Noerr-Pennington*, The Jury's Verdict Barred Smith & Nephew's Antitrust Counterclaim As A Matter Of Law

The district court held that Smith & Nephew's antitrust counterclaim was "premised on the idea that ArthroCare and Ethicon filed 'sham' litigation against Smith & Nephew to prevent or to restrain it from entering the arthroscopic surgery market." A28. The full text of the counterclaim, set forth below (Smith & Nephew omitted the underlined portions from its brief), fully supports this conclusion:

> 30. ArthroCare and Ethicon have engaged in conduct constituting violations of §1 of the Sherman

Antitrust Act by bringing and maintaining this action to restrain competition knowing that '536, '882, and/or '592 patents are invalid, unenforceable, and/or not infringed by any act of Smith & Nephew.

31. ArthroCare's Complaint in this action alleges that Smith & Nephew has infringed the '536, '882, and/or '592 patents. Upon information and belief, at the time ArthroCare filed its Complaint in this action, ArthroCare and Ethicon were aware that the '536, '882, and/or '592 patents were invalid, unenforceable, and/or not infringed by any act of Smith & Nephew.

32. After the California Court had ruled that there were substantial questions as to the validity of the '536 and '882 patents, ArthroCare and Ethicon settled the first ArthroCare case before the California Court made a final ruling on the invalidity of the '536 and '882 patents.

33. In the Settlement Agreement between ArthroCare and Ethicon ("the Settlement Agreement"), ArthroCare agreed, *inter alia*, [

CONFIDENTIAL MATERIAL OMITTED FROM THIS PAGE

].

34. Upon information and belief, ArthroCare and Ethicon settled the first ArthroCare litigation to prevent or restrain other competitors from entering the market, whereby the Settlement Agreement gave to both parties the benefit of any future litigation by splitting any royalties procured through such litigation, even though both ArthroCare and Ethicon knew the '536, '882, and/or '592 patents are invalid.

35. Upon information and belief, ArthroCare and Ethicon have at least a 75% share of the market in the United States for arthroscopic RF surgical devices, which is the relevant market for this antitrust claim.

> This combined market share of at least 75% gives ArthroCare and Ethicon substantial market power and the ability to restrain competition in the relevant market.
>
> 36. This patent infringement action is objectively baseless in that no reasonable litigant could realistically expect success on the merits, particularly in the face of the findings and rulings made in the first ArthroCare litigation. Upon information and belief, ArthroCare commenced and maintained this action despite its knowledge that the '536, '882, and/or '592 patents are invalid, unenforceable and/or not infringed by any act of Smith & Nephew. Upon information and belief, ArthroCare and Ethicon have conspired to commence and maintain this action as an anticompetitive weapon to interfere directly with business relationships of a competitor to the benefit of both ArthroCare and Ethicon.
>
> 37. By conduct alleged herein, ArthroCare and Ethicon have entered into a combination or conspiracy in unreasonable restraint of trade in the relevant market in violation of Section 1 of the Sherman Act, 15 U.S.C. §1, and unless enjoined by this Court there is a dangerous likelihood that ArthroCare and Ethicon will succeed in their conspiracy to restrain trade in the relevant market.

A310-312.

Plainly, the focus of this counterclaim was that ArthroCare and Ethicon commenced and maintained this lawsuit as an anticompetitive weapon against Smith & Nephew. A310 (¶ 30). The *Noerr-Pennington* doctrine immunizes ArthroCare from antitrust liability for bringing this lawsuit. *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508

U.S. 49, 51 (1993). *Noerr-Pennington* likewise immunizes ArthroCare and Ethicon from allegations that they conspired to bring this suit. *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 511 (1972); *McGuire Oil Co. v. Mapco, Inc.*, 958 F.2d 1552, 1558 (11th Cir. 1992). The only way around *Noerr-Pennington* immunity was for Smith & Nephew to establish that the litigation is a "sham." *Professional Real Estate Investors*, 508 U.S. at 56.

With this in mind, Smith & Nephew pleaded four times in its short counterclaim that ArthroCare knew that the patents-in-suit were invalid – classic sham litigation pleading. A310-312 (¶¶ 30, 31, 34, 36).[25] Smith & Nephew also pleaded that ArthroCare's suit was "objectively baseless" – an element of "sham" litigation. In paragraph 36, Smith & Nephew pleaded that ArthroCare and Ethicon brought this suit as "an anticompetitive weapon to interfere directly with business relationships of a competitor" – language taken directly from the *Noerr* decision itself. *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961).

Even counterclaim paragraph 34, which mentions the Settlement Agreement between ArthroCare and Ethicon, is crafted to plead an exception to *Noerr-Pennington* antitrust immunity. Litigation settlements generally are

[25] In setting forth its counterclaim for the Court (Br. 20), Smith & Nephew omitted all four of these sham litigation references.

protected by *Noerr-Pennington* immunity. *Columbia Pictures Indus., Inc. v. Professional Real Estate Investors, Inc.*, 944 F.2d 1525, 1528 (9th Cir. 1991), *aff'd*, 508 U.S. 49 (1993). In seeking to add its antitrust counterclaim, Smith & Nephew acknowledged this general rule: "settlement of patent litigation through licensing agreements [is] generally lawful." A1372. To avoid *Noerr-Pennington*'s protection, and show that the ArthroCare/Ethicon settlement violated the antitrust laws, Smith & Nephew recognized it would need to prove that ArthroCare and Ethicon "enter[ed] into settlement negotiations with the bad-faith awareness of the invalidity or unenforceability of the patent in question." *Id.* (*citing Duplan Co. v. Deering Milliken, Inc.*, 444 F. Supp. 648, 686-87 (D.S.C. 1977)). Plainly, Smith & Nephew crafted paragraph 34 in an effort to fall within the "sham" litigation exception to the antitrust laws.

Thus, accepting the pleaded allegations as true, Smith & Nephew could not have prevailed on its counterclaim, because this lawsuit was not sham litigation as a matter of law. The jury found in favor of ArthroCare on all issues, including validity. A369-378. The district court upheld the verdict in all respects when it denied Smith & Nephew's post-trial motions. Under these facts, ArthroCare is immune from antitrust liability for the counterclaim as pleaded and the district court properly dismissed it. *Professional Real Estate Investors*, 508 U.S. at 60 n.5 ("A winning lawsuit is by definition a reasonable

effort at petitioning for redress and therefore not a sham.").

B. Smith & Nephew's Antitrust Counterclaim Was Properly Dismissed Because It Failed To Allege Antitrust Injury

Antitrust injury is essential to the legal viability of any antitrust claim. *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977) (a plaintiff must prove the existence of "antitrust injury, which is to say injury of the type that the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful").

The only injury that Smith & Nephew pleaded in its counterclaim is its exclusion from, or interference with its business in, the market. A311 ¶¶ 34, 36. These allegations of injury are not actionable, however, because ArthroCare's valid patents – not any agreement with Ethicon – caused Smith & Nephew's exclusion from, and its inability to conduct business in, the alleged market. *Axis, S.p.A. v. Micafil, Inc.*, 870 F.2d 1105, 1111-12 (6th Cir. 1989) (finding no antitrust injury where valid patents prevented the plaintiff from entering market); *accord City of Pittsburgh*, 147 F.3d at 268. Such exclusion is not actionable, and the counterclaim was properly dismissed.

C. The District Court Did Not Err In Rejecting Smith & Nephew's Unpleaded Antitrust Theory

1. Smith & Nephew Never Pleaded The Antitrust Theory Raised In This Appeal

Despite the counterclaim's sham litigation focus, Smith &

Nephew contends that its counterclaim was not limited to sham litigation. Br. 38. Smith & Nephew repeatedly argues that the district court "overlooked," and was "required to accept," its allegation that ArthroCare and Ethicon agreed that ArthroCare would give Ethicon a portion of ArthroCare's future licensing revenues in exchange for Ethicon not challenging the validity of ArthroCare's patents. Br. 3, 23, 38, 41, 42, 43.

The simple fact, however, is that Smith & Nephew **never** pleaded this theory in its counterclaim. The counterclaim never alleges that Ethicon agreed not to challenge the validity of the patents or so agreed in exchange for a share of future licensing revenues. Smith & Nephew cites as "evidence" of the *"quid pro quo"* portions of the Settlement Agreement between ArthroCare and Ethicon. Br. 41. But those citations are improper, because the Settlement Agreement was not attached to or incorporated into the counterclaim and those portions were not cited or quoted in the counterclaim.

The district court was required to decide ArthroCare's motion to dismiss solely on what was pleaded in the counterclaim, and not on briefs, motions, agreements, or evidence in other parts of the record. *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 (3d Cir. 1994); *Jordan v. Fox, Rothschild, O'Brien & Frankel*, 20 F.3d 1250, 1261 (3d Cir. 1994). Thus, Smith & Nephew's challenge must fail.

2. Smith & Nephew's Unpleaded Theory Does Not State A Viable Claim Under The Antitrust Laws

Even had Smith & Nephew pleaded its theory that ArthroCare agreed to share future licensing royalties in exchange for Ethicon not challenging patent validity, which it did not, Smith & Nephew's counterclaim still should have been dismissed.

First, given the important policy of encouraging the settlement of patent litigation, a provision requiring a licensee not to challenge patent validity as part of a settlement agreement should not be objectionable. *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1368 (Fed. Cir. 2001) (holding an accused infringer contractually estopped from challenging the validity of a patent based on an undertaking in a settlement agreement, noting the important policy of enforcing settlement agreements).[26]

Second, Smith & Nephew cannot show that Ethicon's unpleaded

[26] None of the cases cited by Smith & Nephew compels a different result because they concern agreements very different than the Settlement Agreement here. In *Andrx Pharms., Inc. v. Bioval Corp.*, 256 F.3d 799 (D.C. Cir. 2001), the patentee and an ANDA applicant agreed to keep the applicant off the market pending the outcome of a patent infringement suit. Here, in contrast, Ethicon remained in the market and, as Smith & Nephew concedes, ArthroCare was free to license others under the Settlement Agreement. The agreements in the remaining cases are similarly inapposite because they involved *per se* violations of antitrust law, such as industry-wide price fixing (as in *U.S. v. New Wrinkle, Inc.*, 342 U.S. 371, 378 (1952), and *Yarn Processing Patent Validity Litig.*, 541 F.2d 1127 (5th Cir. 1976)) or market allocation (as in *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002)).

agreement not to challenge ArthroCare's patents resulted in the required antitrust injury. Smith & Nephew challenged ArthroCare's patents in court and their validity was upheld. Given that the patents are not invalid, and given that others are free to challenge them, Smith & Nephew cannot show that Ethicon's agreement will "impair competition." Br. 42; *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 138 (E.D.N.Y. 2003) (dismissing Sherman Act claim against settlement agreement that barred one settling party from challenging patent, *inter alia*, because "forcing other generic manufacturers to litigate the validity of the '516 patent" is not injury to competition).

Third, ArthroCare's agreement [

CONFIDENTIAL MATERIAL OMITTED FROM THIS PAGE

].

D. The District Court's Dismissal Did Not Violate Due Process Because Smith & Nephew Was Heard On Its Antitrust Counterclaim

Smith & Nephew's due process rights were not violated. Smith &

Nephew presented and argued its unpleaded antitrust theory to the district court, both before dismissal and after.

When Smith & Nephew moved to add an antitrust counterclaim in 2002, it set forth in its moving papers (but not in its counterclaim) the theory that ArthroCare violated the antitrust laws by [

CONFIDENTIAL MATERIAL OMITTED FROM THIS PAGE

]. A1372, 1375. Although Smith & Nephew did not plead this theory, it clearly apprised the district court of the theory before the counterclaim was dismissed.

Following dismissal, Smith & Nephew again was heard on its antitrust counterclaim when it filed its motion for reconsideration. A18275-18280. There, Smith & Nephew argued that the Settlement Agreement contained a "unique 'kickback' scheme" "devised by competitors jointly comprising a 75% share of the U.S. market for arthroscopic RF surgical devices to maintain their market dominance and drive out remaining competitors like Smith & Nephew." A18278. Smith & Nephew also incorporated by reference its previously filed motion to amend, which recited its unpleaded *"quid pro quo"* theory. A18279.

Because Smith & Nephew presented its antitrust theory to the district court in its motion for reconsideration and its original motion to amend,

there was no due process violation. *Greene v. WCI Holdings Corp.*, 136 F.3d 313, 316 (2d Cir. 1998) (the requirements of due process were met where a litigant has been afforded an opportunity to be heard and "to present [its] case in a meaningful way").

E. Smith & Nephew Has Provided No Grounds For Vacating The Injunction

Smith & Nephew argues if, should the Court remand the antitrust counterclaim for further proceedings, the permanent injunction against further infringement should be vacated. Br. 44-45. This argument is groundless.

First, the infringement determination entitles ArthroCare to an injunction. Courts routinely enter permanent injunctions against patent infringers when antitrust counterclaims remain undecided. *E.g.*, *U.S. Philips Corp. v. National Micronetics, Inc.*, 410 F. Supp. 449, 469 (S.D.N.Y. 1976), *aff'd*, 550 F.2d 716 (2d Cir. 1977) (holding that plaintiff was entitled to a permanent injunction while directing the parties to proceed with defendant's antitrust counterclaim). This is precisely the posture here.

Second, the injunction should stand because Smith & Nephew is highly unlikely to prevail on the merits of its unpleaded antitrust theory. The Agreement between ArthroCare and Ethicon plainly is procompetitive because it allows Ethicon to compete in the market [

CONFIDENTIAL MATERIAL OMITTED FROM THIS PAGE

]. A1481. As Smith & Nephew concedes, ArthroCare has licensed another competitor, Stryker Corporation, [ ]. Br. 43 n.1.

Moreover, Smith & Nephew cannot show that ArthroCare agreed to share a portion of future license royalties in exchange for Ethicon not challenging patent validity. The Agreement expressly provides that the royalty payments to Ethicon are [

CONFIDENTIAL MATERIAL OMITTED FROM THIS PAGE

.]

Finally, Smith & Nephew has utterly failed to establish that the purportedly illegal conduct "constitutes a form of patent misuse." Br. 45. Smith & Nephew has made no showing that the royalty sharing provision of the Agreement is integrally tied to the enforcement of the patents in suit.[27] If

[27] The cases on which Smith & Nephew relies (Br. 45) are simply not on point

the district court were to find the royalty sharing provision improper, it could simply strike that provision from the Agreement, which is, in fact, the specific relief Smith & Nephew prayed for in its amended complaint. A313 (asking the district court to enjoin ArthroCare and Ethicon "by reforming the agreement between them to remove all anticompetitive provisions...").

because none of them involves allegations of injury arising from exclusion from the marketplace based on the enforcement of valid patents.

CONCLUSION AND STATEMENT OF RELIEF

ArthroCare respectfully requests that the Court affirm the district court's denial of Smith & Nephew's motion for JMOL and affirm the dismissal of Smith & Nephew's antitrust counterclaim.

Dated: November 15, 2004

Respectfully submitted,

By: _____

Matthew D. Powers
Jared Bobrow
Perry Clark
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000

Timothy E. DeMasi
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153
(212) 310-8000

Jack B. Blumenfeld
Karen Jacobs Louden
MORRIS, NICHOLS, ARSHT & TUNNELL
1201 North Market Street
Wilmington, DE 19899
(302) 658-9200

Attorneys for Plaintiff/Counterclaim Defendant-Appellee ArthroCare Corporation

CERTIFICATE OF COMPLIANCE

Counsel for ArthroCare Corporation certifies that the foregoing Brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7), in that the word processing system indicates that it contains 13,504 words.

Dated: November 15, 2004

Respectfully submitted,

By: _____

Matthew D. Powers
Jared Bobrow
Perry Clark
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000

Timothy E. DeMasi
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153
(212) 310-8000

Jack B. Blumenfeld
Karen Jacobs Louden
MORRIS, NICHOLS, ARSHT & TUNNELL
1201 North Market Street
Wilmington, DE 19899
(302) 658-9200

Attorneys for Plaintiff/Counterclaim Defendant-Appellee ArthroCare Corporation

CERTIFICATE OF SERVICE

I hereby certify that on November 15, 2004, I caused two copies of the foregoing Nonconfidential Brief For Plaintiff/Counterclaim Defendant-Appellee Arthrocare Corporation to be served by Federal Express to the counsel listed below:

Ruffin B. Cordell
Fish & Richardson P.C.
1425 K Street, N.W., 11th Floor
Washington, D.C. 20005
Telephone: 202.783.5070

Mark J. Hebert
Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: 617.542-5070

Vicki Margolis
Venable LLP
1800 Mercantile Bank & Trust Bldg.
2 Hopkins Plaza
Baltimore, MD 21201
Telephone: 410.244.7400

Executed on November 15, 2004 at Redwood Shores, California. I declare under penalty of perjury that the foregoing is true and correct.

_____
Perry Clark